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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/23/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/747,007	OUELLET ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-28 and 37-49 is/are pending in the application.
- 4a) Of the above claim(s) 20-27 and 37-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-46 is/are allowed.
- 6) ☒ Claim(s) 15-19, 28, 41-43 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of a reply, filed February 10, 2003 as Paper No. 11, to the previous Office Action. Amendments were made to the claims. Specifically, claims 1-14 and 29-36 were cancelled, and new claims 41-49 were added.

Claims 15-28 and 37-49 are pending in the instant application. Claims 20-27 and 37-40 remain withdrawn as being drawn to a non-elected invention. Claims 15-19, 28 and 41-49 are ready for examination in the instant application. Any rejection of record in the previous Office Action, Paper No. 9, mailed October 3, 2002, that is not addressed in this action has been withdrawn.

Because the rejections in this Office Action are either maintained for reasons set forth in a previous Office Action or are necessitated by amendment, this Office Action is made FINAL.

Drawings

New corrected drawings are required in this application because of the reasons set forth on the attached Draftsperson's review (form PTO-948). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Specifically, Figures 1C1-1C5, 6B, 6F, 6I, 6M, 6N, 7A2, 8A, 9A and 10A contain(s) nucleotide sequences that are not identified by SEQ ID NOS, and some of which are not listed in the sequence listing (e.g., the RENT sequences of 1C1-1C5). Applicant is required to provide a new sequence listing, both the paper copy and computer readable format (CRF), including all sequences encompassed by the definitions set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). In addition, applicant must provide a statement indicating the paper copy and CRF are the same, and that they do not incorporate new matter into the instant specification. Finally, applicant is required to amend the specification to clearly identify the sequences with their appropriate SEQ ID NO. Applicant is advised that the sequences present in the Figures can be identified in the Brief Description of the Drawings, provided the indication is clear.

In this instance, the nature of the non-compliance with 37 C.F.R. 1.821-1.825 does not preclude the examination of the application on the merits, the results of which are communicated below. However, failure to comply with all of the requirements of 37 C.F.R. 1.821-1.825 in response to this Office Action will be considered non-responsive.

Claim Objections

Claim 47 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claim 47 recites "open" language (e.g., comprising) whereas the claim from which it depends, claim 44, recites more "closed" claim language (e.g., consisting). Because the dependent claim recites "open" claim language, it broadens the scope of the more narrowly defined independent claim.

Claim 48 is objected to for referring to non-elected subject matter. Specifically, claim 48 refers to SEQ ID NO: 1 in the body of the claim, although it appear to be a typographical error wherein it should refer to SEQ ID NO: 6.

Claim Rejections - 35 USC § 112

Claims 15-19, 28, 41-43 and 48-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the limitation, "provided that, if a native form of the nucleic acid comprises the sequence of SEQ ID NO: 6, then the nucleic acid comprises two, or more than two regions having the nucleotide sequence of SEQ ID NO: 6" is not supported by the instant specification. **This is a new rejection necessitated by amendment.**

Applicant points to several locations in the specification wherein it is purported that the indicated limitation has literal support in the specification. While the recited locations do have support indicating that the nucleotide sequence represented by SEQ ID NO: 6, when placed in tandem, has enhanced translational activity, there is no indication of the limitation wherein said

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tandem sequence is within a native sequence. Specifically, applicant refers to the tandem sequence as being present in pYE2L2GUS, tCUP2 2XL2, etc.; however, these are clearly not the native venue for SEQ ID NO: 6 as the sequence is manipulated in order to be placed in those locations. Similarly, there is no limitation stating that any sequence described in the instant specification must have two or more copies if it is located in a native sequence. As a result, there is no support for the limitation, "provided that, if a native form of the nucleic acid comprises the sequence of SEQ ID NO: 6, then the nucleic acid comprises two, or more than two regions having the nucleotide sequence of SEQ ID NO: 6," therefore the amendments introduce new matter into the specification and claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-19, 28, 41-43 and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Miki et al. (US Patent No. 5,824,872; henceforth Miki). **This rejection is both maintained for reasons set forth in the previous Office Action, and necessitated by amendment as applied to newly added claims 41-43 and 47-49.**

As it regards claims 41-43 and 47-49, the claims are anticipated for the same reasons set forth in the previous Office Action. These claims are addressed specifically below.

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Claims 41-43 are drawn to constructs comprising a nucleotide sequence as defined in claims 17 (claims 41 and 43) and 19 (claim 42). The reasons why claims 17 and 19 are still rejected will be addressed in the "Response to Arguments" section. Because Miki anticipates constructs comprising SEQ ID NO: 6 as defined in claims 17 and 19 in operative association with a gene and regulatory elements (such as a promoter), as set forth in the previous Office Action, Miki also anticipated claims 41-43.

Claim 47 is drawn to a construct *comprising* a sequence as defined by SEQ ID NO: 6, despite the "closed" language of independent claim 44, because claim 47 reintroduces "open" language (also see the objections to the claims). Therefore, the claim again reads on any construct in which SEQ ID NO: 6 appears, which is again anticipated by Miki for the reasons set forth in the previous Office Action.

Specifically with regard to claims 48 and 49, these claims again reiterate "open" language as it concerns the presence of SEQ ID NO: 6 in a nucleic acid (claim 48) and in a construct (claim 49). Miki claims a sequence of which a portion is 100% identical to that of SEQ ID NO: 6, and absent evidence to the contrary, this sequence will hybridize to SEQ ID NO: 6. Miki also describes using this sequence in a construct in operative association with both a gene of interest and a regulatory element. Therefore, Miki anticipates the newly added claims 48 and 49.

Response to Arguments Regarding Claim Rejections Under 35 USC § 102

Applicant's arguments filed February 10, 2002 have been fully considered but they are not persuasive. Applicant's arguments consist of the following points:

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1. The amendment of the claims to contain the limitation "provided that, if a native form of the nucleic acid comprises the sequence of SEQ ID NO: 6, then the nucleic acid comprises two, or more than two regions having the nucleotide sequence of SEQ ID NO: 6" distinguishes the claimed subject matter from that taught by Miki.
2. Miki does not disclose or suggest any specific regulatory property associated with nucleotides 1-24, 1-16 or 10-24 or oligomers of SEQ ID NO: 6 as defined in the instant specification; e.g., that these sequences are capable of regulating translation.
3. That the claims, as amended, now explicitly reflect specific portions of the sequences taught by Miki that are not anticipated by Miki.

The aforementioned arguments are not persuasive for the following reasons:

1. Notwithstanding the lack of literal support in the specification for the amendment to the claims, Miki teaches the sequence comprising SEQ ID NO: 6 as it exists in a non-native environment, thus meeting the limitation of the claim. Support for this statement comes from the following: a) Miki claims an *isolated* sequence comprising SEQ ID NO: 6, therefore the sequence is no longer *native* (e.g., in the environment in which it is originally found- the genome of an organism; this is a reasonable definition provided *in absentia* of a clear definition of "native" in the instant specification) and is not required to comprise two copies of the sequence as per the limitations of the claims; b) Miki identifies the sequence comprising SEQ ID NO: 6 using a T-DNA tagging methodology, wherein the GUS gene is introduced into the genome of a host organism, thereby rendering the sequence which is identified as comprising SEQ ID NO: 6 as no longer native.

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2. That Miki does not disclose a translational activity associated with a nucleic acid comprising SEQ ID NO: 6 is irrelevant because this activity is an inherent property of the sequence.

Applicant is reminded that they are claiming the sequence itself, and not a method of using the sequence to regulate translation.

3. The claims that stand rejected under 35 USC 102(b) are not explicitly defined, as applicant suggests. The claim language "comprising" constitutes "open" language. This means that the sequence can be part of a larger sequence, so long as the entire indicated sequence (in this instance SEQ ID NO: 6) is present within the larger sequence. Miki clearly describes a larger sequence which comprises the entire SEQ ID NO: 6, which necessarily includes nucleotides 1-16 and 10-24.

In conclusion, the limitations of the claims as amended are still met by the teachings of Miki, thus the rejection under 35 USC 102(b) is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 15-19, 28, 41-43 and 47-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,824,872 (henceforth the '872 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because applicant is claiming a genus of sequences wherein a species in said genus has already been patented. **This rejection is both maintained for reasons set forth in the previous Office Action, and necessitated by amendment as it concerns newly added claims 41-43 and 47-49.**

The double patenting rejection as it concerns newly added claims 41-43 and 47-49 is set forth for the same reasons for which the newly added claims have been rejected under 35 USC 102(b), with the key issue being that, although the '872 patent does not teach the translational regulatory activity of SEQ ID NO: 6, this is an inherent property of the nucleic acids being claimed in both the '872 patent, which comprise SEQ ID NO: 6 of the instant application, and the claims of the instant application, directed to sequences that comprise SEQ ID NO:6.

Response to Arguments Regarding the Rejections Under Double Patenting

Applicant's arguments filed February 10, 2002 have been fully considered but they are not persuasive. These arguments are identical to the arguments relating to the traversal regarding the rejections under 35 USC 102(b). Similarly, the response to the arguments are identical to those recited in the "Response to Arguments Regarding Claim Rejections Under 35 USC 102" outlined above, with the key argument being that the translational regulatory activity, although not explicitly taught in the '872 patent, is an inherent property of the sequences and constructs being claimed by virtue of their comprising a sequence identical to SEQ ID NO: 6 of the instant

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application. Therefore the claims of the instant application are obvious in light of the claims of the '872 patent because of the inherent activity of the sequences.

Allowable Subject Matter

Claims 44-46 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
April 21, 2003

DAVID GUZO
PRIMARY EXAMINER
